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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/849,404	05/22/97	LAFFEND	L CR-9715-B

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HM22/1123

EXAMINER

BUGAISKY, G

ART UNIT

PAPER NUMBER

1653

22

DATE MAILED:

11/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/849,404

Applicant(s)
Laffend et al.

Examiner
Gabriele E. Bugaisky

Group Art Unit
1653



☒ Responsive to communication(s) filed on 2/24
Aug 9, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2, 6, 20-31, and 34 is/are pending in the application.

Of the above, claim(s) 34 is/are withdrawn from consideration.

☒ Claim(s) 20-30 is/are allowed.

☒ Claim(s) 2, 6, and 31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 2, 6, 20-31, and 34 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Continued Prosecution Application

The request filed on 2/24/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/849404 is acceptable and a CPA has been established. An action on the CPA follows.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Claims 2, 6, 20-31 and 34 are currently pending.

Election/Restriction

Newly submitted claim 34 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 34 is drawn to the chemical compound 1, 3 propanediol, whereas claims 2, 6 and 20-31 are drawn to a process of making the compound. A compound is not defined by its method of production. Furthermore, the compound is not classified in classes 435 or 536, in which the recombinant method of production has searched.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 34 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Drawings

The formal drawings submitted 2/99 has been approved by the draftsman.

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 6 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-16 of U.S. Patent No. 5,686,276 in view of Daniel *et al.* (1992), in light of Daniel *et al.* (1995). The claims of the patent are to a process for production of 1, 3- propane diol, with a substrate other than glycerol or dihydroxyacetone. They do not specify that the bacteria be transformed with an exogenous *dhaT* gene. Daniel *et al.* provides transformed *E. coli* which express the *Citrobacter freundii*

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dha regulon and produce active glycerol dehydratase; the presence of which is assayed by measurement of 1,3-propanediol production. They do not use a substrate other than glycerol or dihydroxyacetone. Daniel *et al.* later stated that the cosmid used in their earlier work which contained the *dha* regulon also contained the 1, 3-propanediol dehydrogenase gene (*dhaT*). In order to produce 1, 3- propane diol, with a substrate other than glycerol or dihydroxyacetone, it would have been obvious to use the transformed *E. coli* of Daniel *et al.* in the process of U.S. Patent No. 5,686,276, with a reasonable expectation of success in obtaining 1, 3- propane diol.

Applicants have stated in their response of 2/99 that a terminal disclaimer will be submitted. The Examiner is obligated to maintain the rejection until a proper terminal disclaimer is recorded.

Claim Rejections - 35 USC § 112

Claims 2, 6 and 31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of generating 1, 3- propane diol with microorganisms transformed with the *Klebsiella pneumoniae dhaB* gene, does not reasonably provide enablement for production of 1, 3 propane diol by any microorganisms transformed with any diol dehydratase gene from any other organism or with microorganisms containing an endogenous *dhaB* gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant application shows the production of 1, 3- propane diol from organisms transformed with the glycerol dehydratase gene of *Klebsiella pneumoniae*, but does not address how to purify or isolate any other dehydratase genes from any other organism.

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No teaching is given regarding sequence similarity either between *dhaB* genes of different organisms or between dehydratase genes in general. Indeed, Bouvet *et al.* performed an exhaustive survey of glycerol dissimilation of 1,123 strains from 128 taxa in the *Enterobacteriaceae*, and observed only 8 species and a few rare strains could anaerobically utilize glycerol (i.e. possess the *dha* regulon). It is deemed that the scope of the claims is much broader than the enablement provided by the specification and that undue experimentation would be involved in obtaining other dehydratase genes with which to practice the claimed invention.

Applicant's arguments filed 2/99 have been fully considered but they are not persuasive. It is stated that claims 2, 6 and 31 are drawn to a process limited to a dehydratase enzyme and that claims 2 and 31 are further limited to the use of a glycerol dehydratase. It is stated in the response that the specification in combination with the knowledge of the state of the art at the time the invention was made enables the identification, isolation and expression of non-*Klebsiella* dehydratases without requiring undue experimentation. Again, It is noted that the claims are not directed to a method of isolating a *dhaB* gene from other species. A method of obtaining a gene does not enable production of a compound with a gene that may or may not be isolated by those methods. A gene is not described by its method of purification; if one is not in possession of a gene, then how can one be considered enabled in a method of its use in a recombinant process?

Conclusion

Claims 20-30 remain allowed.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 1:30 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER


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November 22, 1999